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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

IN RE BIOVIE INC. SECURITIES LITIGATION.	Case No. 3:24-cv-00035-MMD-CSD **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiff Dr. Anthony Rinaldi and additional named plaintiff Mark Hill (collectively, "Plaintiffs") allege the following upon information and belief, except as to those allegations concerning themselves, which are alleged upon personal knowledge. Plaintiffs' information and belief is based on the investigation of their undersigned counsel, which included, among other things, review and analysis of: (a) public statements made by or on behalf of BioVie Inc. ("BioVie" or the "Company"), including public filings with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases; (c) reports of securities and financial analysts; (d) news articles; (e) industry reports; and (f) interviews with former employees and/or

contractors of BioVie. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CLAIM

1. Biopharmaceutical companies must obtain permission from the U.S. Food & Drug Administration ("FDA") before selling a drug to the public. To obtain this permission, companies need to prove that their drug is both safe and effective through a series of clinical tests performed under strict guidelines and industry standards. This process ensures that patients are protected from dangerous treatments and not made sicker by the medications they were led to believe would make them healthy again. Consequently, for good reason biopharmaceutical companies risk severe penalties and sanctions when they fail to comply with the rules and regulations around clinical testing, such as clinical holds (*i.e.*, stop-work orders), rejection of applications for marketing approval, civil fines, and even criminal penalties.

2. The fallout from botched clinical testing can also have staggering implications for investors. Biopharmaceutical companies are relatively risky investments to begin with. That said, when investors buy stock in drug companies, they do so based on the risk/reward profile the company describes through its public statements, presentations, and SEC filings. Investors rely on that information and make informed decisions about whether the investment is worth the price they would have to pay or simply too risky to get involved. If a biopharmaceutical company lies about the status of its clinical trial program or the risks it currently faces, then investors are not given a fair opportunity to make an informed decision and, accordingly, end up being wrongly deprived of the full disclosure they deserve under the federal securities laws.

3. This is unfortunately what happened to Plaintiffs. In December 2022, BioVie was in the midst of its "pivotal" trial for NE3107, which was referred to as the NM101 study. Internally, clinical trial staff discovered evidence of patient data fraud. This led to a "for-cause" audit by an independent third-party consultant who found evidence of falsified medical history records. The auditor recommended that BioVie cease study enrollment and close the site.

4. By regulation, the December 2022 audit was reported internally and escalated to BioVie's senior management, including the Company's Chief Executive Officer, Defendant

Cuong Do, and Chief Medical Officer, Defendant Joseph Palumbo. But instead of heeding the audit's warnings, they disregarded them, continued enrolling and testing ineligible patients in the NM101 study, and even publicly promoted the Company's trial progress in the press to gin up investor interest for the benefit of raising additional working capital in various at-the-market offerings. Plaintiffs and other investors purchased BioVie's stock in these at-the-market offerings, without any information edgewise about the Company's decision to knowingly rely on fraudulent patient data for its most important pending clinical trial.

5. The trial protocol violations and fraudulent patient data did not subside. They continued unabated over the next several months until August 2023 when, shockingly, a second "for-cause" audit was triggered for the same test site that resulted in nearly identical findings of additional fraudulent patient data. Among other things, MRI reports were not obtained in accordance with trial protocol or industry standards (including the formal standards referred to as Good Clinical Practices or GCPs that are widely used throughout the biopharmaceutical industry), multiple patients presented with verbatim diagnoses received from the same treatment facility on the same day, and medical records were unsigned and contained contradictory patient information. These findings were, according to the auditor, strong evidence of fraud and necessitated further investigation to determine the root cause of the missing data and/or inability to validate the data in the patient files. BioVie, Do, and Palumbo, for a second time, disregarded the warnings and persisted with the study and the fraudulent data.

6. The trial protocol violations and patient fraud extended beyond just the one site at issue in the December 2022 and August 2023 audits. Defendants ultimately revealed in November 2023 that up to ***fifteen test sites*** had produced patient data that could no longer be trusted, leaving BioVie with patient data from just 81 out of 439 enrolled patients; put differently, BioVie had to discard upwards of ***80% of all patient data*** from the NM101 study due to patient fraud and data integrity concerns. Upon BioVie's disclosure of the NM101's study protocol violations and results, the Company's stock plummeted to $1.96 per share, a decline of roughly 60% in the span of a single day.

7. BioVie's public investors sustained significant investment losses as the Company's stock price plummeted. To recover these losses, Plaintiffs bring this lawsuit on behalf of themselves and all persons similarly situated who purchased BioVie common stock between December 7, 2022 to November 28, 2023, inclusive (the "Class Period"), alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5(b).

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has subject matter jurisdiction over this action under Section 27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. § 1331.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

11. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in this District.

PARTIES

12. Lead Plaintiff Dr. Anthony Rinaldi purchased BioVie securities at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in BioVie is incorporated herein by reference. *See* ECF No. 6-2.

13. Additional named plaintiff Mark Hill purchased BioVie securities at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud. Mark Hill's certification evidencing his transaction(s) in BioVie is filed herewith.

14. Defendant BioVie's principal executive offices are located at 680 W. Nye Lane, Suite 204, Carson City, Nevada 89703. During the Class Period, BioVie's securities traded in an efficient market on the Nasdaq under the symbol "BIVI". BioVie is currently at risk of being delisted from the Nasdaq due to noncompliance with listing rules and/or requirements. BioVie has until October 15, 2024 to regain compliance by *inter alia* increasing its bid price for its common stock to above the minimum $1/share threshold.

15. Defendant Cuong Do ("Do") has served as BioVie's President and CEO since April 2021 and at all relevant times thereafter.

16. Defendant Joseph Palumbo ("Palumbo") has served as BioVie's Executive Vice President and Chief Medical Officer since November 2021 and at all relevant times thereafter.

17. Defendants Do and Palumbo are collectively referred to herein as the "Individual Defendants."

18. Each of the Individual Defendants:

(a) directly participated in the management of BioVie;

(b) was directly involved in the day-to-day operations of BioVie at the highest levels;

(c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(d) was directly or indirectly involved in the oversight or implementation of BioVie's business and/or finances, medical, or scientific research;

(e) was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning BioVie; and/or

(f) approved or ratified these statements in violation of the federal securities laws.

19. Because of the Individual Defendants' positions within BioVie, they had access to undisclosed information about the true nature of and risks inherent in the Company's NM101 study.

20. As officers of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's NM101 study and to correct any previously-issued statements that had become materially misleading or untrue.

21. The Individual Defendants, because of their positions with BioVie, possessed the power and authority to control the contents of BioVie's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

22. Each of the Individual Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of BioVie's securities by disseminating materially false and misleading statements and/or concealing material adverse facts. This scheme caused Plaintiffs and other shareholders to purchase BioVie's securities at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

A. *Regulatory Background.*

23. Federal law requires pharmaceutical companies to obtain permission from the FDA before marketing a drug to the public and, in turn, generating revenue from sales. To obtain permission, a company (or sponsor) must demonstrate that the drug is safe, effective, and that its benefits outweigh its risks. This is typically done through clinical trials and the submission of a

New Drug Application ("NDA"). All drugs currently marketed within the United States were, at some point, the subject of an approved NDA.

24. A properly submitted NDA provides the FDA with all pertinent information about the drug, including data and statistical analyses sufficient to determine whether: (1) the drug is safe and provides the benefits it purports to; (2) the benefits of the drug outweigh its risks; (3) the drug's proposed labeling is appropriate and what it should contain; and (4) the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. Although safety and efficacy are particularly important in the FDA's assessment, each of these issues is independently critical to the agency's ultimate approval decision.

25. In order to meet these standards, drug developers typically subject a drug candidate to a series of clinical trials designed to accumulate the data required to submit a successful NDA. Phase 1 clinical trials typically evaluate an investigational drug's safety and dosage tolerance. Phase 2 clinical trials: (1) usually involve larger patient populations; (2) evaluate dosage tolerance and appropriate dosage; (3) identify possible short-term adverse effects and safety risks; and (4) provide a preliminary evaluation of the efficacy of the drug for specific indications. Finally, Phase 3 clinical trials test for efficacy and safety in an even further expanded patient population. Phase 3 trials also usually involve comparison with placebos and are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling.

26. The clinical trial process is heavily regulated. Drug companies, or sponsors, must comply with various regulatory schemes including *inter alia* the Federal Food, Drug, and Cosmetic Act (Title 21 of the U.S. Code of Federal Regulations) as well as the Guideline for Good Clinical Practice (which is an international standard for designing, conducting, recording, and reporting clinical trials that involve human subjects based on the Declaration of Helsinki and other internationally recognized ethical guidelines).

B. *NE3107 and BioVie's NM101 Phase 3 Clinical Trial.*

27. In June 2021, BioVie acquired the biopharmaceutical assets of NeurMedix, Inc., a related party privately held clinical-stage pharmaceutical company and related party affiliate.

These assets included BioVie's lead drug candidate referred to as "NE3107". According to BioVie, NE3107 had the potential to be "an entirely new medical approach" to treating Alzheimer's disease and Parkinson's disease which "affect[] an estimated 6 million Americans suffering from Alzheimer's and 1 million from Parkinson's."

28. On August 5, 2021, BioVie initiated a "pivotal" Phase 3 clinical trial for NE3107 referred to as "NM101". The term "pivotal" has special meaning in the context of FDA clinical trial procedure; it refers to the particular study that the sponsor, or drug company, will primarily rely upon in its NDA for marketing approval from the FDA. NM101 was a randomized, double-blind study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease. BioVie told investors initially that the study would be completed in late-2022 but then extended the target completion date to mid-2023.

29. The NM101 study was material to investors, as evidenced by analyst commentary from top-tier investment banks. For example, on March 14, 2022, Oppenheimer initiated coverage at "outperform" with a price target of $9/share on the basis of NE3107, writing in pertinent part that: "Our bullish view is based on lead candidate NE3107 with an anti-inflammatory and insulin-sensitizing approach to neurodegeneration. NE3107 is an oral inhibitor of inflammatory ERK signaling that could reduce neuroinflammation in Alzheimer's disease (AD) and Parkinson's disease (PD). We believe that emerging literature and prior preclincial and clinical data support this novel MOA [mechanism of action]. Ph3 trial of NE3107 in AD is ongoing with data expected ~YE21 [sic], and Ph2a trial of NE3107 in PD data are expected in 2Q22. We forecast peak sales for NE3107 of ~$1.3B for AD and ~$0.4B for PD in 2031, and apply our respective 50% and 20% POS estimates. Our $9 PT is driven by DCF valuation."

30. Similarly, on July 22, 2022, Cantor Fitzgerald initiated coverage at "overweight" with a price target of $7/share. In pertinent part, the report explained its rating and target as follows: "We are initiating coverage of BioVie (BIVI) with an Overweight rating and a 12-month PT of $7. BioVie is a Neuro-Innovator developing NE3107 ('3107), an orally bioavailable anti-inflammatory insulin sensitizer that binds to a key inflammation cascade mediator (ERK, extracellular signal-regulated kinases) and crosses the blood-brain barrier and may prove to be a

disease-modifying, or at least a symptomatic, treatment for neurodegenerative diseases. The company's lead program is in Alzheimer's disease (AD), for which it is conducting a P3, potentially registrational, trial that is guided to read out in 2H23."

31. Alongside Cantor Fitzgerald's commentary about NE3107's "potential blockbuster opportunity" in treating Alzheimer's disease, the report also struck an ominous note about BioVie's "scientific rigor." In pertinent part, the report said: "That said, we have concerns pertaining to the company's development strategy that modulate our projected probabilities of success. To begin with, BioVie has not conducted dose-ranging studies for its neuro programs. As such, we view the 20mg BID dose being used in the ongoing studies as a bit of a 'dart throw', and we remain uncertain as to whether this is an optimal dose. In addition, for the P3 AD study [NM101], the company doesn't have a screen in place to ensure it enrolls patients with neuroinflammation or insulin resistance. Furthermore, the study is only 26 weeks in length as opposed to the 52 weeks generally used for a disease-modifying therapy for AD. ***Although we applaud management's efforts to be capital-efficient, we are concerned that this is coming at a cost to scientific rigor***" (emphasis added).

C. *BioVie Receives a "For Cause" Audit for Study Protocol Violations.*

32. Unbeknownst to the public, Cantor Fitzgerald's "concerns" about BioVie's "scientific rigor" were all too prescient. By September 2022, BioVie had enrolled approximately 150 patients in NM101 and was preparing for a data review by the study's data safety monitoring board or DSMB. DSMBs are independent groups of experts that provide oversight to drug companies conducting clinical trials. They review study data, protocol, and procedures and are empowered to make recommendations as to the continuation, modification, or termination of a trial. The DSMB's review was scheduled for late-2022.

33. Following preparation for the DSMB review, BioVie was forced to undergo a "for-cause" audit at one of NM101's main study sites (*i.e.*, Site No. 145 located in Cutler Bay, Florida). The audit was conducted by Pitts Quality Consulting on December 28 and 29, 2022. At the time of the audit, the site had enrolled 43 patients (out of approximately 150 patients total). The purpose of the audit was to assess the site's compliance with NM101's study protocol, GCPs (Good

Clinical Practices), applicable regulations, standard operating procedures, and the adequacy of study monitoring occurring at the site.

34. A "for-cause" inspection of a clinical trial is an investigation into a specific problem that has come to either the FDA's attention or the attention of the study's investigator or sponsor (*i.e.*, BioVie). These inspections are not common and may be triggered by complaints, sponsor concerns, or other reasons. For example, a for-cause inspection may occur if there is reason to believe a site has quality problems or to follow up on complaints or evaluate corrections made to address previous violations. Complaints or violations can relate to possible noncompliance, data discrepancies, or ethical concerns.

35. When Pitts Quality Consulting conducted the audit, Site No. 145 was under an enrollment hold (meaning that NM101's principal investigator and/or BioVie had paused enrollment in light of potential misconduct). The audit concluded that the site's level of compliance was unacceptable due in part to evidence of potential misconduct. Site monitoring was also found to be inadequate based on the audit findings. The auditor recommended that BioVie continue the enrollment hold and close the site due to the extent of noncompliance identified.

36. The noncompliance identified during the audit consisted of critical, major, and minor observations. The most significant observations concerned protocol compliance, including that the eligibility of subjects in the NM101 study could not be confirmed due to lack of data integrity of patient medical history records and that patient testing was not being administered uniformly across patients due to different individuals rating patient responses using different languages. Other protocol violations included the enrollment of a site employee's family member without institutional review board approval and failure to translate the testing materials given to patients who required translations.

37. Due to the for-cause nature of the audit, heavy focus was given to subject eligibility which included a focused review on documentation of historical evidence of impairment. The auditor found data integrity issues and irregularities for several subject medical histories. Specifically, patient medical records appeared to be falsified so as to render patients "eligible" for the NM101 study when in fact they were not. The auditor noted that text in the electronic medical

records appeared to be inserted (because it was formatted differently than surrounding text) and dates for patient treatments appeared to be fake (because they postdated the date of the record itself, meaning that the treatment occurred after the date of the medical record). Other signs of fraud included differing header dates on the tops of pages within a single medical record, the absence of print and/or fax dates on medical records, and the absence of diagnosis dates for Alzheimer's disease diagnoses.

38. The auditor concluded that study eligibility could not be confirmed due to the lack of integrity in the medical records (*e.g.*, print/fax date discrepancies compared to dates in the medical records, unexplainable change in fonts for Alzheimer's disease diagnoses, and other documentation anomalies). Additional signs of fraud included six subjects receiving an Alzheimer's disease diagnosis on the same day with half of them coming from the same medical office. The diagnoses were also provided vie telemedicine.

39. The auditor also focused on patient assessment issues, which included inconsistent patient testing resulting from different staff members rating patients differently and using different languages. Translations for testing materials were also not provided to patients that did not speak English. Patients were rated in English at certain times and then Spanish at other times.

40. The auditor noted that Cognitive Research Corporation was the clinical research organization tasked with monitoring site compliance. It conducted monitoring visits every six to 10 weeks with each visit lasting one to two days. Despite the frequency with which Cognitive Research Corporation monitored the site, the auditor concluded that its monitoring was inadequate given that the above issues were not reported.

41. Based in part on the above findings, the auditor concluded that the site's level of compliance was unacceptable due to critical findings and evidence of potentially falsified medical history records. Site monitoring was also determined to be inadequate based on the audit findings which were not identified and/or escalated. The auditor recommended that BioVie cease enrollment and close the site due to the extent of the non-compliance identified.

42. The auditor discussed the audit findings with site personnel at the audit closing meeting on December 29, 2022. Personnel in attendance at the closing meeting included Dr. Carlos

Martinez (Principal Investigator), Gilberto Reyes (Clinical Research Coordinator), Jonathan Dominguez (Clinical Research Coordinator), Yelaine Marichal (Clinical Research Coordinator), Yelenup Gonzalez (Clinical Research Coordinator), Jose Acosta (Clinical Research Coordinator), Jose Marichal (Site Director), and Maria Rodriguez (Clinical Research Associate from BioVie's clinical research organization, Cognitive Research Corporation). Following the closing meeting, BioVie received the auditor's report for review and acceptance, and was required to provide a written response concerning corrective actions.

D. ***Defendants Sell Shares to Retail Investors Amidst Internal Red Flags of Fraud.***

43. While BioVie internally was dealing with damning evidence of protocol violations and data falsification at NM101's key test site (indeed, it was responsible for nearly a third of the study's patients), externally the Company was selling millions of dollars of shares to public investors through at-the-market offerings.

44. On August 31, 2022, BioVie entered into a sales agreement with Cantor Fitzgerald and B. Riley Securities pursuant to which the Company could sell shares into the open market. Between December 14 and 21, 2022, BioVie sold approximately 1.4 million shares of stock to the public pursuant to this agreement.

45. These sales generated approximately $15 million in cash for BioVie. For context, BioVie had approximately $45 million in cash as of December 31, 2022, meaning that the Company's at-the-market offerings during December 2022 accounted for approximately one-third of the BioVie's liquidity.

46. Between December 21, 2022 and April 3, 2023, BioVie sold an additional 3.6 million shares to public investors, raising an additional $19.8 million. For context, BioVie had approximately $31.2 million in cash as of March 31, 2023, meaning that the Company's at-the-market offerings between December 2022 and April 2023, accounted for approximately two-thirds of the BioVie's liquidity

47. BioVie at no point during its at-the-market offerings disclosed the protocol violations and data falsification findings to the public.

48. Due to the at-the-market offerings, BioVie raised enough cash to sustain operations that it otherwise would not have been able to sustain. According to analysts, BioVie's cash following the at-the-market offerings rendered the Company "financially well-positioned," which was a "key point" to analysts and material in terms of their ratings for BioVie in early-2023.

E. ***NM101's Trial Misconduct and Protocol Violations Continue Unabated.***

49. BioVie either intentionally or recklessly disregarded the conclusions from the December 2022 audit because the issues identified at that time (by Pitts Quality Consulting) continued into and throughout 2023. This is confirmed by the findings of yet another "for-cause" audit conducted by GeoSera, Inc., on August 8 and 9, 2023.

50. On August 8 and 9, 2023, GeoSera conducted a "for-cause" audit on Site No. 145 located in Cutler Bay, Florida. This was the same site audited by Pitts Quality Consulting in December 2022. The audit concluded that source documentation for study participants was unacceptable, including MRI reports noted to have been altered to the degree where potential misconduct called for further assessment to determine the validity of the MRIs submitted for the NM101 study.

51. The audit identified three critical observations, four major observations, and one minor observation. The three critical observations concerned MRI reports appearing to have been modified in the demographics section and on the signature section of the reports, multiple MRI results containing the exact same assessments for multiple patients, and discrepancies within medical records concerning demographic information such as date of birth and also procedure dates and times. The major observations concerned record-keeping procedures that violated standard practices, such as overwriting reports instead of adding supplemental reports, unsigned reports, inconsistent notes to files, and missing contemporaneous documentation for MRIs and other evaluations. Finally, the minor observation related to missing information in patient files concerning where patients received MRIs. Collectively, these observations resulted in an "unsatisfactory" audit rating because the observations were critical and amounted to evidence of fraud.

52. At the time of the audit, enrollment at the site was completed. Jose Marichal, the site administrator, and Jonathan Dominguez, the clinical research organization monitor from Clinical Research Corporation, participated in the audit and were present for both the initial and closing meetings on August 8 and 9, 2023, respectively.

53. With regard to the critical observation concerning data validity, the auditor detailed findings relating to files and medical records belonging to over 30 patients (noting that more would have been examined but for time constraints). According to the auditor, the 30 patient files were highly suspect and indicative of fraudulent activity because the patient files *inter alia*:

a) contained exact, verbatim MRI findings, diagnoses, and reports;

b) contained missing information in the source data, such as dates and locations of examinations;

c) were missing entire MRI reports and/or contained reports that were entirely redacted for unknown reasons;

d) contained unsigned medical reports;

e) contained reports that pre-dated diagnostic tests; and

f) contained inconsistent patient data (*e.g.*, dates of birth) from record to record.

54. These findings were concluded to be highly suspect and indicative of fraudulent activity. The MRI reports were not obtained in accordance with GCPs, which rendered the data acquired from the MRI reports in question in terms of use for the NM101 study. The auditor recommended further investigation to determine the root cause of the missing data and/or inability to validate the data in the patient files in order to confirm whether the patients were eligible for the final data analysis for the NM101 study.

55. In light of the findings above, the auditor concluded that the clinical research organization should have halted the study at this site but did not do so despite more than a dozen multiple-day monitoring visits. Likewise, the auditor noted that the site was allowed to update patient files with notes that did not contain the information required to validate underlying source data which, in turn, prevented site staff from properly evaluating eligibility for the study.

F. *Investors Discover Defendants' Fraud.*

56. On November 8, 2023, the Company filed its quarterly report with the SEC on Form 10-Q for the quarter ended September 30, 2023. Defendant Do signed the report on behalf of BioVie.

57. In the quarterly report, BioVie disclosed that:

> [D]uring routine monitoring of blinded data from our Phase 3 study (NCT04669028) of NE3107, we uncovered what appears to be potential scientific misconduct and significant non-compliance with GCPs and regulation at six sites. We have alerted the FDA's Office of Scientific Integrity ("OSI") about these issues and believe OSI will perform a thorough, competent, objective and fair research of any potential scientific misconduct and non-compliance of GCPs and regulation. Sensitivity analysis excluding data from these six problematic sites has been performed and accounted for in the statistical analysis plan for the study (NCT04669028). Nonetheless, these findings of potential scientific misconduct and significant GCP violations may call into question the rigor, robustness and validity of the entire data set for this study (NCT04669028) and may require additional clinical studies to confirm the final results of the study.

58. On November 9, 2023, the price of BioVie stock fell to a low of $2.31 per share, down from its closing price of $4.26 the day before. However, BioVie's stock price remained artificially inflated as a result of Defendants' failure to disclose the full extent of the adverse findings regarding the scientific misconduct and significant non-compliance with GCPs and other regulations.

59. On November 29, 2023, BioVie filed a current report on Form 8-K. The Form 8-K indicated the Company "issued a press release and posted on its website at https://BioViepharma.com/ an investor presentation disclosing top line data from its clinical trial of NE3107 in the treatment of mild to moderate Alzheimer's Disease."

60. A copy of the press release was attached to the Form 8-K. The press release stated in pertinent part that:

> The trial started during the COVID-19 pandemic when access to clinical sites was limited and enrolled a total of 439 patients through 39 sites. Upon trial completion, the Company found significant deviation from protocol and Good Clinical Practice (GCP) violations at 15 sites (virtually all of which were from one geographic area). This highly unusual level of suspected improprieties led the Company to exclude all patients from these sites and to refer them to the U.S. Food and Drug Administration (FDA) Office of Scientific Investigations (OSI) for further action. After these exclusions, 81 patients remained in our Modified Intent to Treat (MITT)

population, 57 of whom were in the Per-Protocol population which included those who completed the trial and were verified to take study drug from pharmacokinetic (PK) data.

61. A copy of the investor presentation was also attached to the Form 8-K, which provided further information about the "significant deviation from protocol" mentioned in the press release. Specifically, the slides indicated that:

- The Company monitors blinded data to track safety and ensure timely data entry into the EDC
- The company started noticing unusual data patterns when enough patients completed the trial. Pentara (a leading AD biostatistics firm) reviewed the blinded data and found:
  - Several sites had anomalous data (e.g. inconsistent patterns compared to historical data, large proportions of patients improving compared to baseline, unusual variability patterns)
  - All patients in a particular demographic group enrolled in this trial showed a data pattern not explainable based on disease progression and which substantially deviated from historical data far this demographic in other AD trials
  - Without unblinding and PK data, there was no way to identify the cause. Clear subgroup analyses identified: anomalous sites vs. other sites; identified demographic group vs. all others
- In parallel, BioVie had the first opportunity to start the data review process as sites started to finish patient-facing activities in early summer 2023
  - Noticed deviations from expectations (e.g. data patterns, missing data, copied/pasted MRI results, etc.)

. . .

- CROs identified six sites with numerous and significant procedural deviations, which led us to:
  - Updated SAP to 1) exclude all patients from affected sites; and 2) pre-specify a series of subgroup analyses
  - Amended our protocol: 1) Finalize CDR-SB and ADAS-Cog12 as primary endpoints based on prior FDA communications; 2) Created "adaptive trial" design
  - Reported the 6 sites to the FDA's Office of Scientific Investigations
- As data was unblinded, anomalous data from the identified demographic group was confirmed to be scientifically improbable. Furthermore, all patients in this demographic were associated with the previously identified anomalous sites, and virtually all of which were concentrated in a single geographic area. Accordingly, these sites were also excluded per our SAP and additionally referred to the FDA.

62. The presentation also noted that "Unanticipated exclusion of sites due to deviations led to study being underpowered. Adaptive feature of trial allows the Company to continue enrolling patients to reach statistical significance."

63. On the same day, BioVie hosted a conference call which was led by Defendants Do and Palumbo, as well as the CEO of Pentara Corporation. On the call, Defendant Do noted that the NM101 trial "did not achieve statistical significance because we had to exclude so many patients from the trials that we believe engaged in improper practices." He further noted that BioVie had to exclude 358 patients, which represented "over 80% of our enrolled populations due to suspected improper conduct at 15 clinical sites," and that "all of these clinical sites had been referred to the FDA."

64. Defendant Do acknowledged that what BioVie found at the affected clinical sites was "so unusual" and explained why BioVie believed it had to exclude the 356 patients. He stated that each site was responsible for uploading data to an electronic database known as the "EDC" for its patients, that the EDC is maintained by the CRO, and that BioVie only had read access to the blinded data. Do noted that the Company "monitors blinded data on an ongoing basis to review safety and ensure that data is entered on a timely basis into the EDC."

65. With regard to six of the clinical sites excluded, Defendant Do stated:

> In parallel, patient facing activities started to wrap up at some of the sites in July of 2023, which provided us the first opportunity to conduct a detailed data review and validation….that is when we started to notice higher than expected levels of deviations….that is when we made the decision to undertake a multi-step review process that involved hiring a supplemental CRO to conduct quality control visits to all sites and then to conduct source data verification or SDV on 100 percent of the materials touched in the clinical sites. Subsequently, a third CRO was hired to audit sites as well. We took this level of proactive actions and diligence that goes way above what is typically done by pharma companies because we understood the importance of this data. We finally received the final QC reports from the supplemental CRO on November 6th, which revealed that six sites that enrolled 128 patients had what appeared to be numerous and significant GCP violations and deviations from our protocol. The deviations were to such an extent that we had to act.
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> [W]hen we saw this problem we acted rapidly and vigorously, rather than ignore it because we could not condone the practices we uncovered, such as when multiple patients came in for an MRI scan on the same day they ended up having the same

result posted with their records…as a result we did the following: first we updated our statistical analysis plan or SAP to exclude all data from these six deviating sites because the patients and their data were totally suspect. Second, we amended our protocol with the FDA to do two things – first is that we finalize the primary endpoints to be CDR-SB and ADAS-Cog. This was a planned activity as a result of our interaction with the FDA over months…the second thing is that we revised the clinical trial design itself to be an adaptive design so that we may work with the FDA to potentially continue enrolling additional patients if we see an efficacy signal but miss on stats due to the excluded sites. And the third thing we did was referred all six sites to the FDA's Office of Scientific Investigations three days after receiving the CRO's report….on November the 9th.

66. With regard to the other nine sites that were excluded, Defendant Do explained:

When we started unblinding the data, we focused first on the sub-group analyses that Pantera recommended, right, and we found that the anomalous data from the patients from the identified demographic groups could not be explained scientifically. The placebo patients are not expected to significantly and dramatically improve as we saw in the data from this demographic group. The same thing was found regarding the anomalous sites. And, in fact, the problem identified with the demographic group and the anomalous sites turned out to be one and of the same in that virtually all patients from the demographic group were associated with the anomalous sites, which were all located in one geographic area. Thus, we had to exclude these nine sites that enrolled a total of 230 patients as well per our pre-specified SAP. Since virtually all of the now 15 sites suspected of improprieties were in a single geographic area, we suspect that there may be more going on; thus, we referred all 15 sites to the FDA. And since we have a deep respect for the FDA and their investigative processes we are not identifying the geographic area and sites and we have not notified any of the sites as to their status… by excluding 358 patients or over 80% of our enrollment we were left with 81 patients in our modified intent to treat population. This also meant that we only had 57 in the per protocol populations, which are patients who have completed the trial, patients who we can verify have taken the study drug through PK, and so forth.

67. Defendant Do then addressed how such an issue arose:

So the natural question is how could this have happened? That is a great question and I wish I had a simple, great answer for you. But, I believe there are a few confounding factors that got us here. First, we started enrolling the trial at the height of the COVID-19 pandemic, where there was limited access to the sites. In fact, the limited access remained the case for most of the duration of the trial. We rely on third-parties to execute and monitor the trials so one could say the on the ground oversight of the sights [sic] was not what it needed to be. Second, we assumed good intent. There are nearly 500,000 clinical sites registered in clinicaltrials.gov, all of whom are licensed. They have to adhere to GCP, and they are periodically audited by the FDA and other agencies. We presumed that our clinical sites would act responsibly, but we found ourselves victim of suspected coordinated improprieties at a level that none of us have seen in our careers. It's just so unusual. There's just no other way of describing it.

68. During the question-and-answer portion of the call, Defendant Do acknowledged that:

> What's very very clear to us here is that monitoring, on-site monitoring of what was going on was not where it needed to be, right, and so frankly one of the things we will do is what I have done for my other clinical trials in Asia for example, is we are going to take a belt-and-suspenders approach, right? In those trials I always have my own CRAs alongside the CRO's monitors out at the sites, right, and we are essentially going to go with more established sites that have conducted more of these Alzheimer trials, and frankly we have changed our CRO. And so those are some of the things that we will be doing immediately and we will be working…to identify the other safeguards that we need to put in place – along with the FDA – I think the FDA will have a point of view kind of given the bit of a scandal that we have here with these sites.

69. Another analyst questioned Defendant Do about the "big picture," asking:

> What gives you confidence, excluding these patients, that the data holds, and what would motivate a region, not just one clinical trial site to actually, you know, not run the trial the way it is designed? Like what really happened?

70. Defendant Do responded:

> I don't want to start any conspiracy theories or anything else like that. And it's actually the vast majority or virtually all of 15 sites are in the same geographic area, right, and that is the reason why we have referred this thing on to the FDA to investigate because we would be just speculating, right? We do know in certain other disease that there is phenomena [of] professional patients that may be part of what is going on here but I am not going to speculate anything else.

71. On November 29, 2023, the stock closed at $1.96, down more than 60% from the previous day's closing price of $4.99.

FALSE AND MATERIALLY MISLEADING STATEMENTS

December 7, 2022

72. On December 7, 2022, BioVie filed a current report on Form 8-K with the SEC attaching a letter to shareholders and an investor presentation. Defendant Do signed the letter to shareholders.

73. In pertinent part, the letter to shareholders stated:

> We also recently announced that ***BioVie's Phase 3 trial in AD has fully enrolled the targeted 316 patients*** and that the company is opting to increase study size to 400 due to our fast enrollment pace. The trial protocol specified enrolling at least 316 patients. The protocol also pre-specified the potential for a review when roughly 50% of the 316 enrolled patients have completed the study to determine if

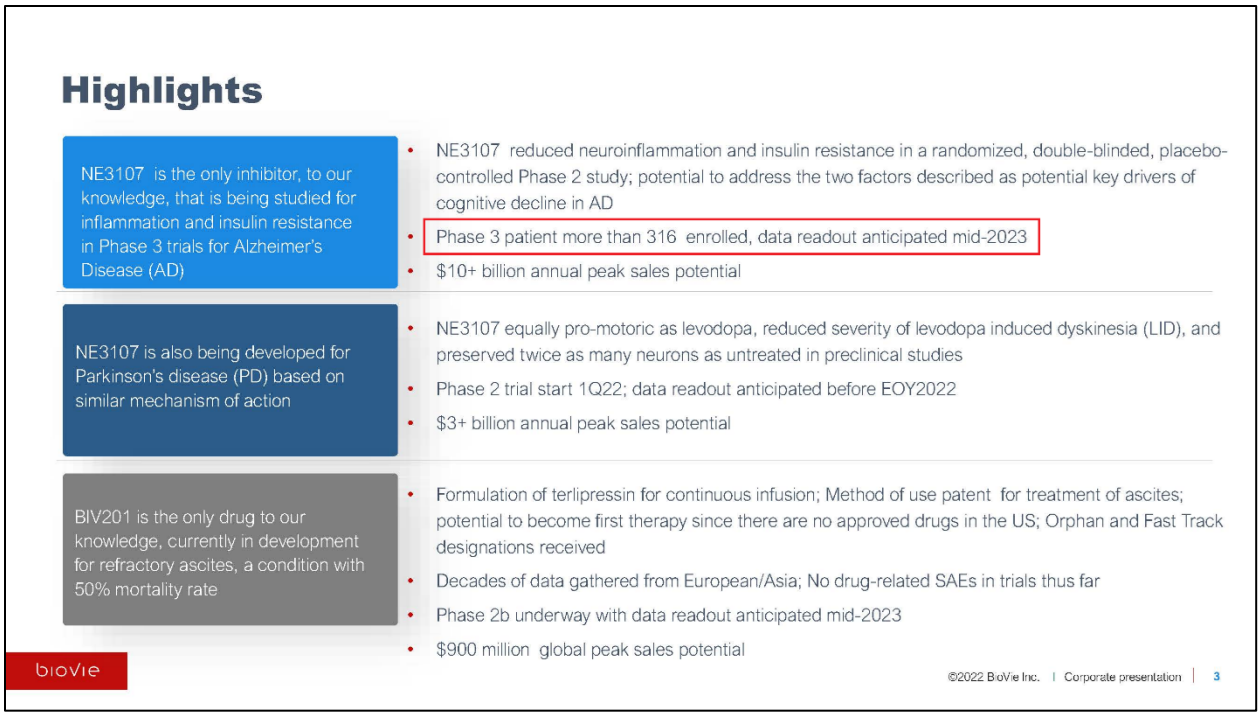
> increasing enrollment of up to 400 patients might be desirable for the purpose of enhancing the probability of achieving statistical significance. The pace of enrollment increased dramatically in recent months, creating a situation where the Company finished enrolling all 316 patients before 50% of enrolled patients had completed the study. ***Thus, we decided that forgoing the interim analysis and continuing enrollment up to 400 patients is the best course for obtaining the strongest possible data set***. We believe all 400 patients can be enrolled in the coming months and anticipate topline results will be available before the end of 3Q2023. By taking this step we believe we have enhanced our probability for success, and thus our ability to bring this hoped for innovation to the Alzheimer's patient community.

(Emphasis added)

74. The statements identified above in emphasis were false and/or materially misleading because the NM101 study was not "fully enrolled" pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

75. In addition, BioVie stated publicly that it was "forgoing" the DSMB review and proceeding to enroll additional patients in order to "obtain[] the strongest possible data set." However, the then-current "data set" included fraudulent data and/or data from ineligible patients. Additional data was therefore necessary to maintain the "power" of the study pursuant to NM101's study protocol. Consequently, the above statements were false and/or materially misleading insofar as they concealed the significant problems with the data already in BioVie's possession and misrepresented the reasons for needing or wanting additional data, *i.e.*, to replace the fraudulent data while maintaining sufficient "powering" without having to abort the trial and start anew.

76. The investor presentation contained similar statements, including the following slide reiterating the enrollment information for NM101:



77. The statements identified above in the slide were false and/or materially misleading because the NM101 study had not enrolled "more than 316" patients properly and in accordance with the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

February 10, 2023

78. On February 10, 2023, BioVie filed its quarterly report on Form 10-Q with the SEC for the period ended December 31, 2022. Defendant Do signed the report on behalf of BioVie.

79. In pertinent part, the quarterly report made the following claims about the NM101 study's enrollment and targets for completion:

> In neurodegenerative disease, the Company acquired the biopharmaceutical assets of NeurMedix, Inc. ("NeurMedix"), a privately held clinical-stage pharmaceutical company, in June 2021 (See Note 5 Related Party Transactions). The acquired assets included NE3107, a potentially selective inhibitor of inflammatory extracellular single-regulated kinase ("ERK") signaling that, based on animal studies, is believed to reduce neuroinflammation. NE3107 is a novel orally administered small molecule that is thought to inhibit inflammation-driven insulin resistance and major pathological inflammatory cascades with a novel mechanism of action. There is emerging scientific consensus that both inflammation and insulin resistance may play fundamental roles in the development of Alzheimer's Disease (AD) and Parkinson's Disease (PD), and NE3107 could, if approved, represent an entirely new medical approach to treating these devastating conditions affecting an estimated 6 million Americans suffering from AD and 1 million Americans suffering from PD. In August 2021, the Company initiated the FDA authorized potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). ***The Company is targeting primary completion of this study in the third quarter of calendar year 2023***.
>
> . . .
>
> The increase in research and development expenses of $1.3 million was primarily due to the Neuroscience NE3107 studies, which were significantly more active during the three months ended December 31, 2022 compared to the three months ended December 31, 2021. The Parkinson's Phase 2 study initiated in January 2022, became fully enrolled with the top-line data read reported in December 2022 and ***the Alzheimer Phase 3 study is approaching full enrollment***. Our Orphan drug candidate BIV201's Phase 2b study, which was initiated in June 2021, accounted for approximately $100,000 of the net increase in research and development expenses for three months ended December 31, 2022.

(Emphasis added)

80. The statements identified above in emphasis were false and/or materially misleading because the NM101 study was not "approaching full enrollment" pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited

to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

81. Relatedly, the above statements concerning the target "completion" of the NM101 study was false and/or materially misleading because it contradicted and concealed the delay that would inevitably be caused by the patient fraud and data integrity issues described above. Once the fraudulent data and/or ineligible patients were removed from the trial, the NM101 study would not be sufficiently "powered" pursuant to the study's protocol. This, in turn, would require additional enrollment or starting the trial anew. In either event, the target completion dates identified above created the materially false impression that the NM101 trial was proceeding properly and in accordance with the study's protocol.

82. The quarterly report also provided investors with a materially misleading description of risks arising from the protocol and compliance violations in the NM101 study, stating in pertinent part that:

> We depend, and will continue to depend, on contract research organizations ("CROs"), clinical trial sites and clinical trial principal investigators, contract laboratories, and other third parties to conduct our clinical trials. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices ("cGCPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development. Regulatory authorities enforce cGCPs through periodic inspections and for-cause inspections of clinical trial principal investigators and trial sites. ***If we or any of these third parties fail to comply with applicable cGCPs or fail to enroll a sufficient number of patients***, we may be required to conduct additional clinical trials to support our marketing applications, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state, or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or provide us or government agencies with inaccurate, misleading, or incomplete data.
>
> Although we design the clinical trials for our product candidates, our CROs will facilitate and monitor our clinical trials. As a result, many important aspects of our clinical development programs, including site and investigator selection, and the conduct and timing and monitoring of the study, will be partly or completely

> outside our direct control. Our reliance on third parties to conduct clinical trials will also result in less direct control over the collection, management, and quality of data developed through clinical trials than would be the case if we were relying entirely upon our own employees. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities.
>
> Any third parties conducting our clinical trials are not, and will not be, our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, ***if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements***, or if there are other difficulties with such third parties, such as staffing difficulties, changes in priorities, or financial distress, our clinical trials may be extended, delayed, or terminated. As a result, we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates will be harmed, our costs could increase, and our ability to generate revenue could be delayed.
>
> If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to timely enter into arrangements with alternative trial sites or CROs, or do so on commercially reasonable terms. Switching or adding clinical trial sites or CROs to conduct our clinical trials involves substantial cost and requires extensive management time, training, and focus. In addition, there is a natural transition lag when a new third party must learn about our product candidates and protocols, which can result in delays that may materially impact our ability to meet our desired clinical development timelines.

(Emphasis added)

83. The statements identified above in emphasis were false and/or materially misleading because the NM101 trial was already suffering from GCP violations and fraudulent patient data, as evidenced by internal reports and independent third-party auditor reports. Thus, the above statements misled investors by presenting GCP violations and/or compromised data as purely hypothetical when, in fact, they had already occurred.

March 2, 2023

84. On March 2, 2023, BioVie issued a press release titled "BioVie Announces Completion of Patient Enrollment in Phase 3 Trial Assessing NE3107 in Alzheimer's Disease." In pertinent part, the press release stated:

> CARSON CITY, Nev., March 02, 2023 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or the "Company"), a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease, today announced that its NM101 trial evaluating NE3107 in the treatment of patients with Alzheimer's Disease, has ***achieved its revised enrollment target of 400 patients***. The Company anticipates announcing top line results from the study in October 2023.
>
> The NM101 trial is a potentially pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in patients who have mild to moderate Alzheimer's disease (NCT04669028). The study has co-primary endpoints looking at cognition using the Alzheimer's Disease Assessment Scale-Cognitive Scale (ADAS-Cog 12) and function using the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC).
>
> The NM101 trial protocol originally specified enrolling at least 316 patients equally randomized to treatment and placebo arms. The protocol also pre-specified the potential for a review by the data safety monitoring board (DSMB), in a manner that is blinded to the Company, when roughly 50% of the 316 enrolled patients have completed the study to determine if increasing enrollment of up to 400 patients might be desirable for the purpose of enhancing the probability of achieving statistical significance. ***Due to an accelerating pace of enrollment as the trial progressed, the Company enrolled 316 patients before 50% of enrolled patients had completed the study. Consequently, the Company decided to proceed to 400 patients without the pre-specified interim analysis***.
>
> "***We look forward to having topline data from this trial in October***," said Cuong Do, BioVie's President and CEO. "We are optimistic that this trial will provide similar data to what was seen in the Phase 2 exploratory study, which showed that patients treated with NE3107 experienced enhanced cognition as measured by multiple assessment tools, including a 2.1 points improvement on the modified ADAS-Cog12 scale."

(Emphasis added)

85. The statements identified above in emphasis were false and/or materially misleading because the NM101 study had not "achieved" its "enrollment" targets pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits

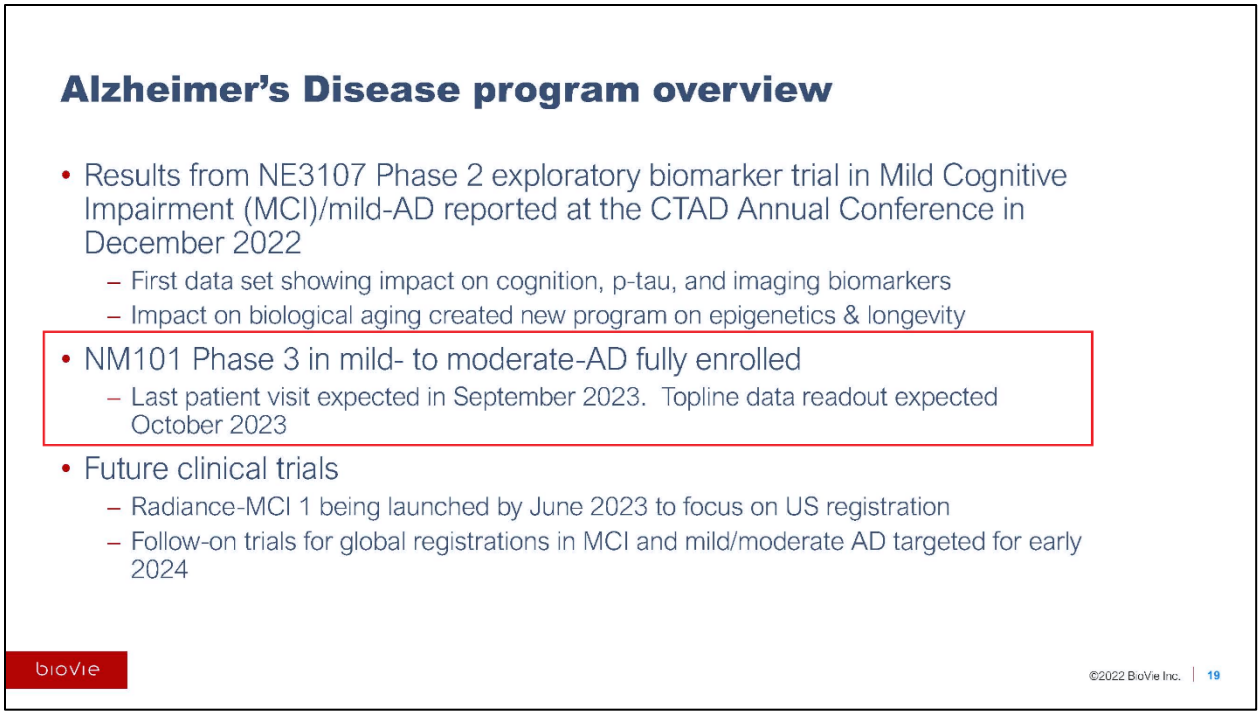
confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

86. Relatedly, the above statements concerning the October date for "topline data" was false and/or materially misleading because it contradicted and concealed the delay that would inevitably be caused by the patient fraud and data integrity issues described above. Once the fraudulent data and/or ineligible patients were removed from the trial, the NM101 study would not be sufficiently "powered" pursuant to the study's protocol. This, in turn, would require additional enrollment or starting the trial anew. In either event, the target completion dates identified above created the materially false impression that the NM101 trial was proceeding properly and in accordance with the study's protocol.

March 23, 2023

87. On March 23, 2023, BioVie filed a current report on Form 8-K with the SEC attaching an investor presentation.

88. The investor presentation provided investors with false representations about the enrollment status and progress of the NM101 trial in terms of its target completion date. In pertinent part, the presentation contained the following slide:

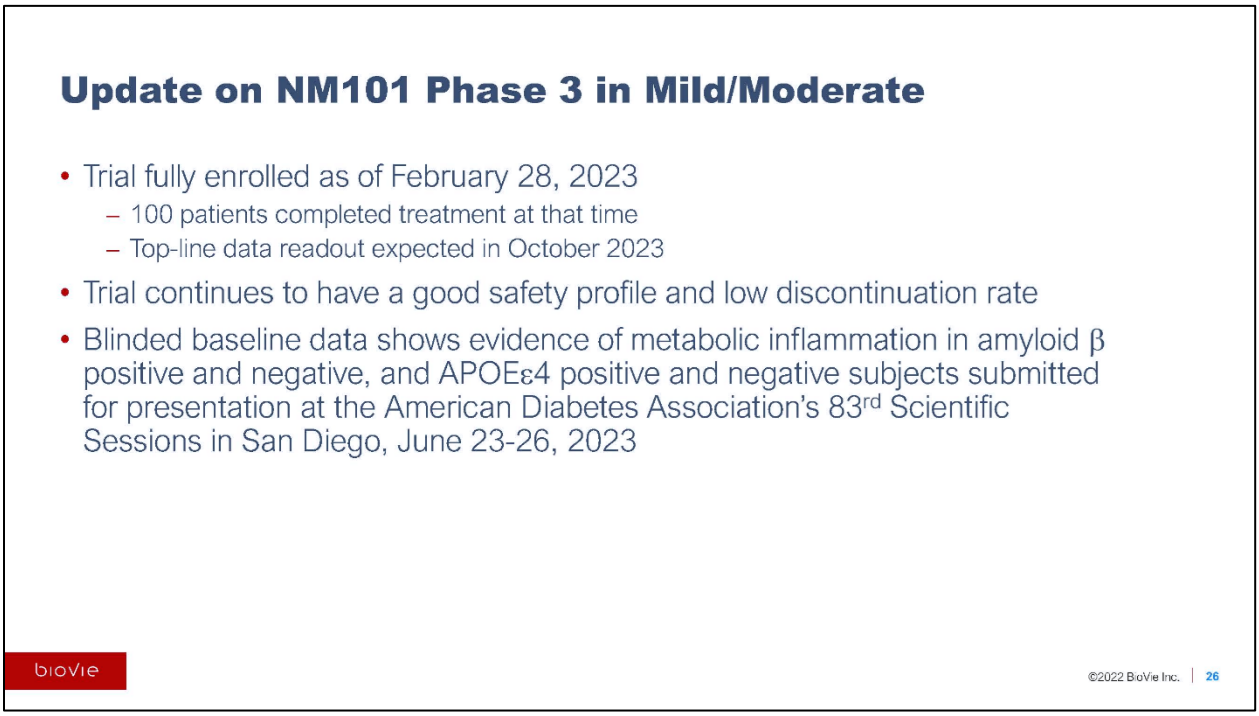


89. The statements identified in the above slides were false and/or materially misleading because the NM101 study was not "fully enrolled" pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

90. Relatedly, the above statements concerning the October date for "[t]opline data readout" was false and/or materially misleading because it contradicted and concealed the delay that would inevitably be caused by the patient fraud and data integrity issues described above.

Once the fraudulent data and/or ineligible patients were removed from the trial, the NM101 study would not be sufficiently "powered" pursuant to the study's protocol. This, in turn, would require additional enrollment or starting the trial anew. In either event, the target completion dates identified above created the materially false impression that the NM101 trial was proceeding properly and in accordance with the study's protocol.

91. In addition, the presentation discussed NM101's data in detail without disclosing its integrity problems, *i.e.*, the fact that included fraudulent patient data. In pertinent part, BioVie provided investors with the following slide:



92. The statements identified in the above slide were false and/or materially misleading insofar as they created a misleading impression of the strength of the data in BioVie's possession at the time of the investor presentation. While the "baseline data" may have showed "evidence of metabolic inflammation" in certain subjects, BioVie concealed that a material number of patients in the NM101 data were either ineligible for the study in the first instance or did not have proper underlying data to confirm their eligibility. Thus, BioVie's description of the study data materially misled investors concerning the strength of the data and/or its ability to sustain the NM101 study at the "power" level required by the study protocol.

May 12, 2023

93. On May 12, 2023, BioVie filed its quarterly report for the period ended March 31, 2023, on Form 10-Q with the SEC. Defendant Do signed the report on behalf of BioVie.

94. In pertinent part, the quarterly report made the following claims about the NM101 study's enrollment and targets for completion:

> The Company acquired the biopharmaceutical assets of NeurMedix, Inc. ("NeurMedix"), a privately held clinical-stage pharmaceutical company, in June 2021 (See Note 5 Related Party Transactions). The acquired assets included NE3107, a potentially selective inhibitor of inflammatory extracellular single-regulated kinase("ERK") signaling that, based on animal studies, is believed to reduce neuroinflammation. NE3107 is a novel orally administered small molecule that is thought to inhibit inflammation-driven insulin resistance and major pathological inflammatory cascades with a novel mechanism of action. There is emerging scientific consensus that both inflammation and insulin resistance may play fundamental roles in the development of Alzheimer's Disease (AD) and Parkinson's Disease (PD), and NE3107 could, if approved represent an entirely new medical approach to treating these devastating conditions affecting an estimated 6 million Americans suffering from AD and 1 million Americans suffering from PD. In August 2021, the Company initiated the FDA authorized potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate AD (NCT04669028). ***The Company is targeting primary completion of this study in the fourth quarter of calendar year 2023***.
>
> . . .
>
> The increase in research and development expenses of approximately $6.7 million was primarily due to the Neuroscience NE3107 studies, which were significantly more active during the three months ended March 31, 2023, compared to the three months ended March 31, 2022. The Parkinson's Phase 2 study initiated in January 2022 reported top results and ***the Alzheimer Phase 3 study reached full enrollment***. Our Orphan drug candidate BIV201's Phase 2b study, which was initiated in June 2021, accounted for approximately $124,000 of the net increase in research and development expenses for three months ended March 31, 2023.

(Emphasis added)

95. The statements identified above in emphasis were false and/or materially misleading because the NM101 study had not "reached full enrollment" pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed

that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

July 18, 2023

96. On July 18, 2023, BioVie published a letter to its shareholders written by Defendant Do. In pertinent part, the letter stated:

> Dear Shareholders,
>
> The company has made tremendous progress since I last wrote you in December, and ***the totality of the data we have shared lead me to be increasingly excited and optimistic about what we hope to see when our Phase 3 trial for NE3107 in Alzheimer's Disease (AD) reads out later this year***. I have prepared this letter to shareholders to provide an update that synthesizes all the information that we have released and presented at recent medical conferences.
>
> . . .
>
> Our NM101 trial has been ***fully enrolled*** since February 2023 and is nearing its completion by the end of September. Topline data readout is expected in the October-November timeframe.
>
> ***As we approach data readout, I am increasingly optimistic about what we hope to see based on the totality of the data that we have disclosed***. The data described above is suggestive that NE3107 may have an active epigenetic effect associated with improvements in inflammation, insulin signaling, and other critical biological processes in a manner that is significantly correlated to improvements in cognition, AD biomarkers, and imaging endpoints. This small exploratory trial involving just 23 patients provided statistically significant data on so many measures and correlations. Assuming that epigenic changes seen in the Phase 2 trial is coming from NE3107 activity and not some placebo or random effect, one would expect the 200 patients treated with NE3107 in the NM101 trial should have dramatically different results from the 200 patients in the placebo arm on these same measures.
>
> Additionally, the data we recently presented at the 83rd Scientific Sessions of the American Diabetes Association that took place June 23-26 give[s] further support for what we can expect. This poster presentation did not provide any results or readouts. Instead, ***it provided the first data on the 400 patients in the NM101 trial as they started the trial (i.e., at baseline)***, including:
>
> - The large majority of patients had elevated inflammatory markers and were overweight. Large portions have some degree of metabolic dysregulation, including hypertension (61%), impaired glucose metabolism (52%), insulin resistance (47%), hypertriglyceridemia (40%) and hypercholesterolemia (30%).

- Patients who are amyloid beta positive (Aβ+) had comparable CDR-SB scores at baseline as those who are Aβ negative (Aβ-). This supports our thesis all along that Aβ cannot be the only factor driving AD or cognitive decline.
- Aβ+ patients had worse ADAS-Cog12 and MMSE scores (indicating lower cognitive functioning) than the Aβ- patients, while the Aβ- patients had significantly higher inflammation, insulin resistance, IFG, and hypertension, compared to their Aβ+ counterparts. We interpret this data to mean that metabolic factors are critical drivers of cognitive decline for everyone, and that the presence of Aβ is a contributory – but not a causal – factor for the cognitive decline.

Patients treated with NE3107 in prior trials have seen improvements in inflammation, glucose metabolism, insulin resistance, hypercholesterolemia, hypertriglyceridemia, etc. We believe the fact that patients started the trial with elevated levels of these factors provides additional cautious optimism for the NM101 trial as NE3107 has demonstrated a potential impact on these areas in previous studies.

(Emphasis added)

97. The statements identified above in emphasis were false and/or materially misleading because they completely concealed the gaping integrity issues that existed with respect to the NM101 study data. Two independent audit reports relating to just one site within the study concluded that patient data was fraudulent. Additional reports of fraud implicated up to 15 sites resulting in the removal of all patient data but for approximately 80 patients out of more than 400 patients enrolled. By claiming the study was "fully enrolled" and referring to the "totality of the data" as supporting a favorable study outcome, the shareholder letter grossly misled investors by portraying the NM101 study as suggesting a reliable and positive result when, in fact, the study was effectively worthless due to rampant protocol violations that had already occurred and were continuing to occur unabated.

August 16, 2023

98. On August 16, 2023, BioVie filed its annual report for the period ended June 30, 2023, on Form 10-K with the SEC. Defendant Do signed the report on behalf of BioVie.

99. In pertinent part, the annual report made the following claims about the NM101 study's enrollment and targets for completion:

In neurodegenerative disease, the Company's drug candidate NE3107 inhibits inflammatory activation of extracellular single-regulated kinase ("ERK") and

> Nuclear factor kappa-light-chain-enhancer of activated B cells ("NFkB") (e.g., tumor necrosis factor ("TNF") signaling) that leads to neuroinflammation and insulin resistance, but not their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both inflammation and insulin resistance are drivers of Alzheimer's disease ("AD") and Parkinson's disease ("PD").
>
> The Company is conducting a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate NE3107 in patients who have mild to moderate Alzheimer's disease (NCT04669028). ***The Company is targeting primary completion of this study in the fourth quarter of calendar year 2023***.
>
> . . .
>
> The Company is conducting a potentially pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in patients who have mild to moderate AD (NCT04669028). The study has co-primary endpoints looking at cognition using the Alzheimer's Disease Assessment Scale-Cognitive Scale (ADAS-Cog 12) and function using the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC). ***The program is fully enrolled and is targeting primary completion in the fourth quarter of the calendar 2023 year***.

(Emphasis added)

100. The statements identified above in emphasis were false and/or materially misleading because the NM101 study was not "fully enrolled" pursuant to the trial's protocol. BioVie enrolled a material number of patients that should not have been enrolled (as many as 80%), thereby contradicting the publicly-stated number of enrolled patients and/or status of patient enrollment in the NM101 study. The December 2022 and August 2023 audits confirmed that patients enrolled in the trial did not meet the eligibility criteria under the study protocol and/or patient data failed to confirm their eligibility for the study. While these audit findings were limited to only one site, BioVie ultimately discarded patient data from up to 15 different sites, leaving the NM101 study with data from only approximately 80 patients. Consequently, the above statements concerning the enrollment status of the NM101 trial were false and/or materially misleading.

101. Relatedly, the above statements concerning the target "completion" of the NM101 study was false and/or materially misleading because it contradicted and concealed the delay that would inevitably be caused by the patient fraud and data integrity issues described above. Once the fraudulent data and/or ineligible patients were removed from the trial, the NM101 study would not be sufficiently "powered" pursuant to the study's protocol. This, in turn, would require

additional enrollment or starting the trial anew. In either event, the target completion dates identified above created the materially false impression that the NM101 trial was proceeding properly and in accordance with the study's protocol.

102. The annual report also provided a materially misleading impression of BioVie's compliance with regulations concerning clinical trials. In pertinent part, the annual report stated:

> In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implements regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, or the PHSA, and related regulations, and other federal, state and local statutes and regulations. Biological products include, among other things, viruses, therapeutic serums, vaccines and most protein products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. ***Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions***. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.
>
> The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following: . . . ***Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug or biologic for its intended use*** . . . .
>
> Clinical trials involve the administration of the drug or biological candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. ***Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety***. Each protocol must be submitted to the FDA as part of the IND. ***Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements***. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

(Emphasis added)

103. The statements identified above in emphasis were false and/or materially misleading because they created the false impression that the NM101 study met the requirements being discussed when, in fact, it did not. Contrary to BioVie's description of clinical trials and the need to comply with applicable regulations, including GCPs, BioVie already had in its possession confirmed reports from at least two independent third-party auditors that the NM101 study data included fraudulent patient data indicating that the study had enrolled patients that should not have been enrolled. This, in turn, subjected BioVie to the precise FDA sanctions that BioVie warned about. However, by concealing the protocol violations within the NM101 study, BioVie concealed from investors the risks they faced concerning these sanctions as well as created the false impression that the NM101 study was being conducted in compliance with applicable regulations, such as the GCPs explicitly mentioned.

104. The annual report also provided investors with a materially misleading description of risks arising from the protocol and compliance violations in the NM101 study, stating in pertinent part that:

> We depend, and will continue to depend, on contract research organizations ("CROs"), clinical trial sites and clinical trial principal investigators, contract laboratories, and other third parties to conduct our clinical trials. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices ("cGCPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development. Regulatory authorities enforce cGCPs through periodic inspections and for-cause inspections of clinical trial principal investigators and trial sites. ***If we or any of these third parties fail to comply with applicable cGCPs or fail to enroll a sufficient number of patients***, we may be required to conduct additional clinical trials to support our marketing applications, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state, or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or provide us or government agencies with inaccurate, misleading, or incomplete data.
>
> Although we design the clinical trials for our product candidates, our CROs will facilitate and monitor our clinical trials. As a result, many important aspects of our

> clinical development programs, including site and investigator selection, and the conduct and timing and monitoring of the study, will be partly or completely outside our direct control. Our reliance on third parties to conduct clinical trials will also result in less direct control over the collection, management, and quality of data developed through clinical trials than would be the case if we were relying entirely upon our own employees. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities.
>
> Any third parties conducting our clinical trials are not, and will not be, our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, ***if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements***, or if there are other difficulties with such third parties, such as staffing difficulties, changes in priorities, or financial distress, our clinical trials may be extended, delayed, or terminated. As a result, we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates will be harmed, our costs could increase, and our ability to generate revenue could be delayed.
>
> If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to timely enter into arrangements with alternative trial sites or CROs, or do so on commercially reasonable terms. Switching or adding clinical trial sites or CROs to conduct our clinical trials involves substantial cost and requires extensive management time, training, and focus. In addition, there is a natural transition lag when a new third party must learn about our product candidates and protocols, which can result in delays that may materially impact our ability to meet our desired clinical development timelines.

(Emphasis added)

105. The statements identified above in emphasis were false and/or materially misleading because the NM101 trial was already suffering from GCP violations and fraudulent patient data, as evidenced by internal reports and independent third-party auditor reports. Thus, the above statements misled investors by presenting GCP violations and/or compromised data as purely hypothetical when, in fact, they had already occurred.

106. BioVie's annual report contained similarly misleading warnings, stating in pertinent part that:

> The process of obtaining FDA approval is costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include, among other things: (a) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (b) filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics; (c) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (d) filing by a company and acceptance and approval by the FDA of a NDA for a drug product or a BLA for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our product candidates through clinical testing and to market, which could have a materially adverse effect on our business.
>
> . . .
>
> Even if we are successful in developing BIV201 and NE3107, our product candidates, we have limited experience in conducting or supervising clinical trials that must be performed to obtain data to submit in concert with applications for approval by the FDA. The regulatory process to obtain approval for drugs for commercial sale involves numerous steps. Drugs are subjected to clinical trials that allow development of case studies to examine safety, efficacy, and other issues to ensure that sale of drugs meets the requirements set forth by various governmental agencies, including the FDA. In the event that our protocols do not meet standards set forth by the FDA, ***or that our data is not sufficient to allow such trials to validate our drugs in the face of such examination***, we might not be able to meet the requirements that allow our drugs to be approved for sale which could have a materially adverse effect on our business.

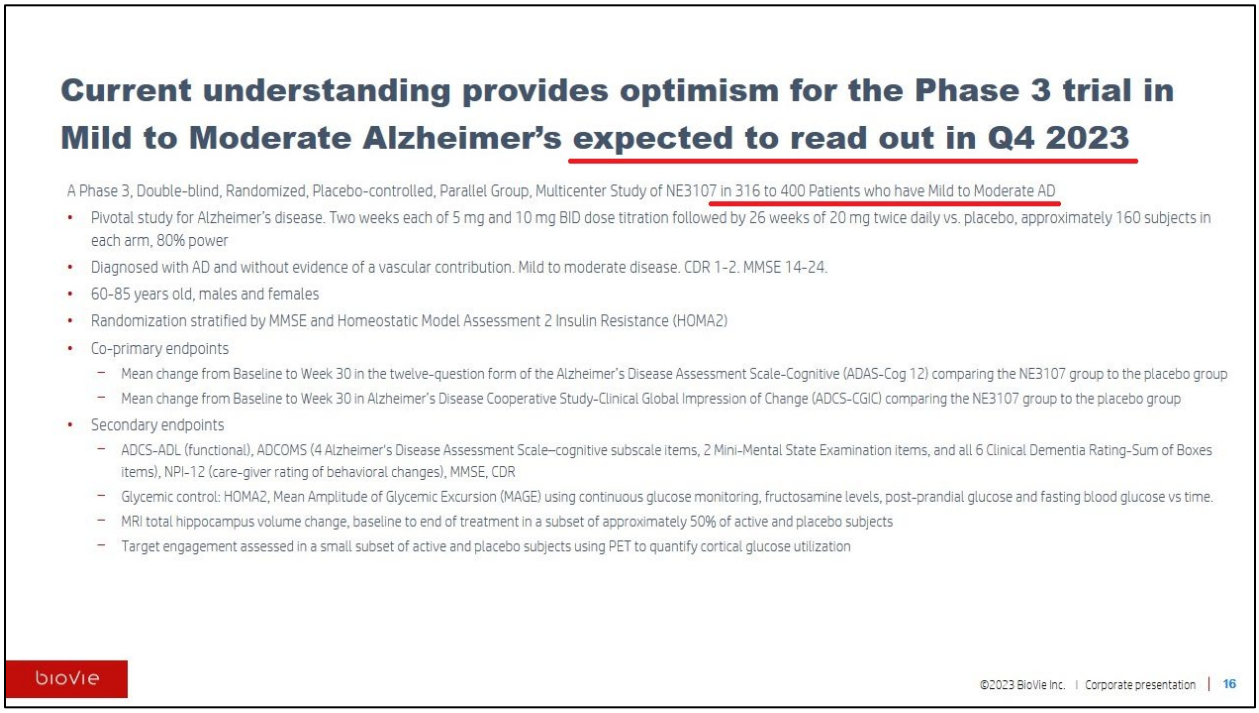
(Emphasis added)

107. The statements identified above in emphasis were false and/or materially misleading because the NM101 trial was already suffering from GCP violations and fraudulent patient data, as evidenced by internal reports and at least two independent third-party auditor reports. Thus, the above statements misled investors by presenting the risk of NM101's study data being "not sufficient" as a mere potentiality when, in fact, it was already known by Defendants that the data was corrupt and would not be accepted by regulatory agencies (including the FDA).

September 8, 2023

108. On September 8, 2023, BioVie filed a current report on Form 8-K with the SEC attaching an investor presentation.

109. The investor presentation provided investors with false representations about the enrollment status and progress of the NM101 trial in terms of its target completion date. In pertinent part, the presentation contained the following slide:



110. The statements identified in the above slides were false and/or materially misleading because the NM101 study had enrolled dozens of patients incorrectly under the study protocol, meaning that any "read out" of data would be severely undermined in terms of credibility and integrity. BioVie already had in its possession confirmed reports from at least two independent third-party auditors that the NM101 study data included fraudulent patient data contradicting the publicly-stated number of enrolled patients in the NM101 study and severely undermining the study's integrity. The fraud was much more pervasive however, extending to potentially 15 sites and ultimately resulting in the removal of all but approximately 80 patients from the study (out of more than 400 patients supposedly enrolled). Consequently, the above statements concerning the upcoming "read out" were false and/or materially misleading.

October 25, 2023

111. On October 25, 2023, BioVie issued a press release announcing the presentation of data from the NM101 Phase 3 clinical trial. In pertinent part, the press release stated as follows:

> Carson City NV, October 25, – BioVie Inc., (NASDAQ: BIVI) ("BioVie" or the "Company") a clinical-stage company developing innovative drug therapies for the treatment of advanced liver disease and neurological and neurodegenerative disorders, announced that blinded data on cognitive, biomarker and imaging findings from the recently completed Phase 3 clinical trial (NCT04669028) of NE3107 in the treatment of mild to moderate Alzheimer's Disease (AD) were presented today as an oral presentation at the 16th Clinical Trials on Alzheimer's Disease (CTAD) in Boston, MA.
>
> The presentation, Clinical Outcomes from a Phase 3, Randomized, Placebo-Controlled Trial of NE3107 in Subjects with Mild to Moderate Probable Alzheimer's Disease, detailed a cross sectional analysis of blinded data from BioVie's Phase 3 study and discussed participants whose data were available for analysis as of October 18, 2023 (n=322). These preliminary analyses will be updated once the complete and final dataset becomes available and when the study database is locked, unblinded and analyzed in full.
>
> ***The blinded data presented suggest that NE3107 is a biologically active compound exerting potential effects as observed by biomarker, imaging, cognitive and functional assessments. Population changes from baseline were observed, with some patients demonstrating an improvement after 30 weeks of treatment with the double blinded oral study drug (NE3107 or matched placebo) as compared to baseline, while many were also observed to have worsened, which is consistent with the natural progression of the disease (Figure 1)***.
>
> . . .
>
> "***The blinded data presented at CTAD show encouraging changes from baseline that would not typically be seen without a treatment effect, which provides us with confidence that NE3107 may show a clear benefit over placebo when the data from this trial is unblinded in the coming weeks***," commented Joseph Palumbo, BioVie's Chief Medical Officer. "We believe NE3107 has the potential become to effective multi-mechanistic treatment for Alzheimer's that is safe and can be orally administered."
>
> The last patient came in for the last treatment visit in late September 2023, and ***the Company is currently resolving outstanding database queries*** and preparing for database freeze and data unblinding. The Company expects to announce unblinded, topline data from this trial in the November/December timeframe.

(Emphasis added)

112. The statements identified above in emphasis were false and/or materially misleading. The protocol violations that occurred during the NM101 study resulted in dozens of patients being enrolled in the study that should not have been enrolled or failed to have underlying

medical records validating their enrollment. Independent reports from at least two auditors in December 2022 and August 2023 concluded that patient data from one site was fraudulent. The fraud was much more pervasive however, extending to potentially 15 sites and ultimately resulting in the removal of all but approximately 80 patients from the study (out of more than 400 patients supposedly enrolled). Consequently, the top line results provided in the above press release materially misrepresented the outcome of the study in light of the gaping data integrity issues that existed at the time.

November 1, 2023

113. On November 1, 2023, BioVie hosted a conference call to discuss the Phase 3 trial. The call was attended by analysts and hosted by Defendants Do and Palumbo. During opening remarks Defendant Do stated:

> ***So we presented the data that we had as of October 18 from roughly 322 subjects, whose data were verified or in the process of being verified and cleaned as of this date***.
>
> . . .
>
> ***And in looking at the totality of the data, we conclude that any NE3107 appears to be biologically active and that it appears to be having an impact on the cognitive biomarkers and end-to-end points that we've looked at in the trial***.
>
> . . .
>
> And as we look at this pattern, we see great -- we have some optimism that there is an effect, a drug effect going on. We need to make that comment because if there were not a drug effect, you would expect all the subjects to be clumped together. And that would be roughly around the no-change line or it's somewhat worsening, somewhat getting better if there's a learning or a placebo effect.
>
> But the fact that we see a pattern of maybe people getting better and many people getting worse, which suggests to us that there is something going on beyond just a group, the drug that not working. You would not see a lot of people getting a lot better if there is not something going on here, right? And the magnitude of the clinical getting better from this blinded data is a little too large from what you would expect from just a placebo effect.

(Emphasis added)

114. Defendant Palumbo followed up with additional comments on the Phase 3 clinical trial, stating:

> ***So [the results tell] us that we've captured the right individuals for this study***. It shows that in the course of only six months, who started out as negative shift,

> towards positive, it gives us a good look at the sensitivity of this study. And that -- and remember, half of these folks are on drug and half are on placebo.
>
> So for me, this is a signal I was looking for in the midst of COVID, in the midst of everything else. Did we capture the right patients and would they progress as expected, right? And you wouldn't necessarily see this in a study that was only looking at positive patients at baseline. Now the data and positivity is great, of course, that we have people who shift towards this negative status, and that is absolutely exciting.
>
> ***Also, this validation study is long enough, at least to me, in looking at the shift from negative to positive in a six-month basis of the study***. And so I'm actually very happy with that. And that was all I really wanted to say, Cuong.

(Emphasis added)

115. During the question-and-answer session Defendant Do stated:

> So with that, I know that we have over time here, let me close the call by saying that ***we are cautiously optimistic when looking at the totality of the data***, right? And I do not believe you can look at any one particular measure to say things are working or not working, ***you have to look at the totality of the data***.
>
> ***And the totality of the data here would suggest that NE3107 appears to have an underlying biological effect and that biological effect appears to be having an impact on the cognitive, functional, biomarker and imaging endpoints that we are looking at in this trial***.
>
> So we are cautiously optimistic that when we unblind the data after Thanksgiving or early December, that this could potentially lead to a significant improvement, a significant new tool for the community to treat Alzheimer's disease when it's fully registered.

(Emphasis added)

116. The statements identified above in emphasis from the conference call were false and/or materially misleading because they completely concealed the gaping integrity issues that existed with respect to the NM101 study data. Two independent audit reports relating to just one site within the study concluded that patient data was fraudulent. Additional reports of fraud implicated up to 15 sites resulting in the removal of all patient data but for approximately 80 patients out of more than 400 patients enrolled. By referring to the "totality of the data" as supporting a favorable study outcome, Defendants grossly misled investors by portraying the NM101 study as having produced a reliable and positive result when, in fact, the study was effectively worthless due to rampant protocol violations that occurred.

ADDITIONAL SCIENTER ALLEGATIONS

BioVie Tried to Conceal, Whitewash, and Ignore the "For-Cause" Audits

117. BioVie hired GeoSera with the understanding that GeoSera would bless the NM101 study's data in advance of regulatory approval. GeoSera is a small independent auditing firm owned and managed by John Carlos Diaz. At all relevant times, Mr. Diaz had close personal relationships with senior level employees of BioVie, including Joseph Palumbo who was BioVie's Chief Medical Officer and Executive Vice President, Head of Research and Development, and David Morse, BioVie's Chief Regulatory Officer and Senior Vice President.

118. BioVie initially hired GeoSera in or around July 2023 to perform quality control and/or assurance on the primary endpoint readings in the NM101 study (*i.e.*, to confirm that the results were accurate). GeoSera, in turn, hired approximately six independent contractors for the project. On August 6, 2023, in the midst of onboarding, a medical monitor for BioVie named Dr. Nily Osman reported potentially fraudulent data relating to MRI reports within patient files in the NM101 study at Site No. 145 in Cutler Bay, Florida.

119. At Dr. Osman's direction, GeoSera dispatched approximately two members of the project team to Site No. 145 to investigate the potential fraudulent patient files. The GeoSera auditors (not Mr. Diaz) confirmed the issues identified by Dr. Osman during the audit that occurred on August 8 and 9, 2023 (discussed above). While conducting the audit, one of the site's owners, Jose Marchial, mentioned to one of the auditors that the site and been audited previously in December 2022 (*i.e.*, the Pitts Quality Consulting audit discussed above), that the site had received a "follow-up" letter from BioVie, that the site had responded to BioVie, but that the site had never received a "close-out" letter. "Close-out" letters refer to written confirmations from auditor and/or sponsor staff that any and all violations identified during the audit have been properly corrected and no longer interfere with the study.

120. The GeoSera auditors were unaware of the December 2022 audit, which was atypical and out of practice. Upon commencing an audit, industry practices ordinarily require site staff and/or study sponsors to provide the auditors with all prior audit materials. The GeoSera auditors then asked Mr. Diaz to obtain a copy of the prior audit materials. Mr. Diaz did not ask for

the audit materials; instead, the GeoSera auditors had to rely on Annette Ferrell (who worked underneath Mr. Diaz) to obtain the audit materials from BioVie. Ms. Ferrell asked Flynn Eldred, BioVie's Vice President, Head of Quality, for the December 2022 audit report. Mr. Flynn initially did not provide the report but reluctantly acceded to the request. At this point, the GeoSera auditors who were tasked with investigating Site No. 145 observed that the issues identified by Pitts Quality Consulting in December 2022 had continued unabated throughout the NM101 study.

121. Following GeoSera's August 2023 audit, Mr. Diaz attempted to dissuade his auditors from doing anything that could compromise his relationship with BioVie. Mr. Diaz communicated this to Ms. Ferrell as well. Mr. Diaz also attempted directly to minimize the potential fallout from the audit by, among other things, reviewing and editing the reports he received from his auditors even though Mr. Diaz did not attend the audit personally. Pursuant to industry practice, audit reports are edited only by the auditors who conduct the audit and should not be edited by anyone else.

122. BioVie also attempted to edit the auditor reports from the August 2023 audit. Specifically, when the auditors submitted the report to Mr. Eldred and Dr. Morse at BioVie, Mr. Eldred told the auditors to remove BioVie as the party responsible for follow-up at the site. Mr. Eldred's efforts to edit the report and, in particular, to remove BioVie as the responsible party were highly irregular and contrary to industry practices. BioVie engaged in other atypical and irregular practices concerning audits for the NM101 study, including sending high-level medical monitors and additional clinical research associates to supposed independent audits conducted by third-party monitors. This occurred in August 2023 in connection with a separate audit of another site (not Site No. 145). Sponsors typically do not have additional staff present for audits being completed by independent auditors in order to preserve the independence and objectivity of the audit.

123. Subsequent to completing the August 2023 audit report, Mr. Diaz retaliated against the auditors who conducted the August 2023 audit. Mr. Diaz refused to pay one of the auditors for the work that was provided and terminated the auditor's contract.

124. Notwithstanding the two separate audits and explicit findings concerning evidence of fraudulent data, BioVie wanted to proceed with the NM101 study data and submit it in support

of an NDA (New Drug Application) for NE3107. Shortly after the GeoSera audit completed, Defendant Do told BioVie's medical monitor, Dr. Osman, that he wanted to disregard the audit findings and proceed with the data as it was. Defendant Do (along with BioVie's Chief Medical Officer, Joseph Palumbo, Chief Financial Officer, Wendy Kim, and Chief Regulatory Officer, Dr. Morse) then prevented Dr. Osman from continuing her medical monitoring review. Instead, BioVie used another third-party auditor named David Diaz who was willing to overlook the data validity issues identified in the previous audits and approve the study data in part on the basis that, according to Mr. Diaz, fabrication of data was not explicitly defined by GCPs. Mr. Diaz's willingness to accept potentially fabricated data was not in compliance with industry standards or customary practices.

125. Defendant Do's scienter is further evidenced by his continued deception following the revelation of the NM101 study misconduct. On November 29, 2023, instead of truthfully telling analysts and investors that he and the Company had received reports of fraudulent data as early as December 2022, Do claimed that BioVie only "started to notice higher than expected levels of deviations" in the data in July 2023 and that they "acted rapidly and vigorously, rather than ignore it because we could not condone the practices [they] uncovered, such as when multiple patients came in for an MRI scan on the same day they ended up having the same result posted with their records." Yet "ignore it" is precisely what they did in response to the second "for-cause" audit findings in August 2023. Do feigned ignorance to maintain public appearances and salvage investor sentiment, further evidencing his scienter during the Class Period.

Defendants Knew of the Fraud or Deliberately Ignored the Red Flags

126. Industry standards, customary practices, and the trial protocol for the NM101 study required BioVie to conduct the NM101 study in compliance with the trial protocol, GCPs, FDA regulatory requirements, and in accordance with the ethical principles of the Declaration of Helsinki. As previously explained, GCPs are international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials.

127. Federal regulations state that "[s]ponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly,

ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug." 21 C.F.R. § 312.50.

128. GCPs state that sponsors are responsible for implementing and maintaining quality assurance and quality control systems with written operating procedures. Specifically, Section 5.1 of the International Conference on Harmonisation (ICH)'s Good Clinical Practice rules enumerates the duties and responsibilities of sponsors in clinical trials. Significantly, Section 5.1.1 states: "The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)."

129. Section 5.1.2 states that: "The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities."

130. Section 5.1.3 states that: "Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly."

131. While a sponsor may transfer trial-related duties to a third-party clinical research organization, the ultimate responsibility for the quality and integrity of the trial data resides with the sponsor. *See* Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance 24 (1996). Section 5.2.1 explicitly states, in pertinent part, that: "A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."

132. Indeed, in its quarterly filings with the SEC, BioVie routinely admitted that: "we are responsible for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third

parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices ('cGCPs'), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development."

133. BioVie disregarded NM101's trial protocol, GCPs, FDA regulatory requirements, and other standards by allowing the study to proceed in the face of red flag warnings about fraudulent data. Independent auditors on at least two occasions notified BioVie that the data being collected in the NM101 was fraudulent. BioVie disregarded these warnings, concealed them from the public, and continued with the trial in violation of clinical trial protocols, practices and standards. Defendants' course of conduct concerning the NM101 study amounted to an extreme departure from ordinary standards of care.

BioVie Desperately Needed Working Capital

134. BioVie was at risk of running out of cash at the start of the Class Period. As of December 31, 2022, the Company had working capital of approximately $38.2 million and an accumulated deficit of approximately $277.1 million. BioVie had not generated any revenue to date and no revenue was expected for the foreseeable future. Indeed, BioVie's future operations were dependent on the success of its ongoing development and commercialization efforts, as well as its ability to secure additional financing.

135. BioVie's quarterly report on Form 10-Q for the period ended December 31, 2022 stated in pertinent part that, "[a]lthough our cash balance may sustain operations over the next 12 months from the balance sheet date if measures are taken to delay planned expenditures in our research protocols and slow the progress in the Company's clinical programs, ***the Company's current planned operations to meet certain goals and objectives project cash flows to be depleted within that period of time***" (emphasis added).

136. When describing its clinical trials and business plan for commercialization, BioVie stated that: "Due to our financial constraints, we do not have the resources necessary to complete all of these clinical studies. Subject to FDA guidance, we plan to commence additional Phase 2 and potentially Phase 3 clinical trials ***upon receipt of a successful capital raise***. There is no

guarantee the FDA will approve the commencement of a Phase 3 trial for BIV201, and even if it does, our financial constraints may prevent us from undertaking clinical trials" (emphasis added).

137. Based on the foregoing, BioVie was under immense pressure to raise working capital from its at-the-market offerings during the Class Period. Without this capital, the Company would have been unable to continue operations, as admitted by BioVie in its filings with the SEC. Thus, its ability to maintain a façade of operational success and progress in terms of its clinical trial plans was paramount; disclosing the compliance and protocol violations in the NM101 study would have severely jeopardized BioVie's ability to obtain working capital (if not killed it altogether).

138. BioVie's need for working capital and, in turn, the need to maintain a successful image with investors provided Defendants with motive and opportunity to commit the fraud alleged herein. Given BioVie's financial straits, this motive surpassed any ordinary or generic corporate motive to raise funds.

Do Falsely Certified Quarterly Reports under Sarbanes-Oxley.

139. As BioVie's CEO, Defendant Do signed each of the Company's quarterly and annual reports, including those containing the false and/or materially misleading statements identified above. In addition, Do certified the contents of those reports pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. "Sarbanes-Oxley Certifications," like the ones signed by Do, are required by Congress and the SEC "to facilitate full disclosure and ensure the accuracy of financial reports by requiring corporate executives' personal stamp of approval." 149 Cong. Rec. S5325, S5329 (daily ed. Apr. 11, 2003).

140. In each instance, Do's certifications were knowingly false. On at least two occasions, members of BioVie's executive leadership received reports from independent auditors detailing evidence of fraudulent data within the NM101 study. Do received these reports through the internal disclosure controls he certified in the above-referenced certifications. Thus, Do knew or deliberately disregarded the falsity of his statements in the Company's SEC filings but certified their accuracy notwithstanding.

LOSS CAUSATION AND ECONOMIC LOSS

141. The market for BioVie common stock was open, well-developed, and efficient at all relevant times. As a result of Defendants' false and/or materially misleading statements, BioVie's stock traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased BioVie stock relying upon the integrity of the market and market information related to the Company and have been damaged thereby.

142. Defendants' false and/or materially misleading statements about BioVie's NM101 Phase 3 clinical trial constituted a scheme to deceive the market and a course of conduct that caused the price of BioVie's stock to be artificially inflated. As Defendants' misrepresentations and fraudulent conduct were gradually disclosed and became apparent to the market, the artificial inflation in the price of BioVie's stock was removed, and the price of BioVie stock fell. Plaintiffs and other investors sustained damages as the risks concealed by Defendants' fraudulent statements materialized and/or the truth emerged concerning BioVie's NM101 Phase 3 clinical trial.

143. On November 8, 2023, after market hours, BioVie filed its quarterly report on Form 10-Q for the quarter ended September 30, 2023. In pertinent part, the quarterly report revealed that BioVie had "uncovered . . . potential scientific misconduct," leading investors and the market at large to doubt the credibility and/or reliability of the NM101 clinical trial's results. In response to the news, BioVie's stock price declined from $4.26 per share on November 8, 2023 to $3.01 per share on November 9, 2023.

144. On November 29, 2023, before market hours, BioVie released its topline data from the NM101 Phase 3 clinical trial. In pertinent part, BioVie disclosed that it "found significant deviation from protocol and Good Clinical Practices (GCP) violations at 15 sites (virtually all of which were from one geographic area)" necessitating the exclusion of "all patient[]" data from these sites. The disclosure provided further confirmation that the NM101 Phase 3 clinical trial was lacking in terms of credibility and/or reliability, and that further studies would be necessary in order to bring NE3107 to market. In response to the news, BioVie's stock price declined from $4.99 per share on November 28, 2023 to $1.96 per share on November 29, 2023.

145. The disclosures identified above on November 8 and 29, 2023, contradicted Defendants' fraudulent statements and/or revealed to investors (first, in part, and then, in whole) that BioVie's NM101 Phase 3 clinical trial presented abnormal, undisclosed, and exceedingly atypical risks in light of the significant trial misconduct and protocol violations that occurred. Thus, Defendants' fraud proximately caused the decline in BioVie's stock price when the truth emerged concerning BioVie's NM101 Phase 3 clinical trial.

146. Alternatively, the risks concerning trial misconduct and protocol violations that had previously been concealed by Defendants through their fraudulent statements ultimately materialized as BioVie announced the above adverse information concerning the NM101 Phase 3 clinical trial. This, in turn, caused investor losses as the market reevaluated the risks associated with investing in BioVie.

147. As a result of their purchases of BioVie stock during the Class Period at artificially inflated prices, Plaintiffs and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

148. The timing and magnitude of the price decline in BioVie stock negate any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

PRESUMPTION OF RELIANCE; FRAUD-ON-THE-MARKET

149. At all relevant times, the market for BioVie stock was an efficient market for the following reasons:

(a) BioVie met the requirements for listing, and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) As a regulated issuer, BioVie filed periodic public reports with the SEC and the Nasdaq;

(c) BioVie communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and

through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) During the Class Period, on average, hundreds of thousands of BioVie shares were traded on a weekly basis. On news days, the Company's trading volume increased, reflecting an active trading market for BioVie stock and investors' expectations being impounded into the stock price.

150. As a result of the foregoing, the market for BioVie's securities promptly digested current information regarding BioVie from all publicly available sources and reflected such information in BioVie's stock price. Under these circumstances, all purchasers of BioVie securities during the Class Period suffered similar injury through their purchase of BioVie securities at artificially inflated prices, and a presumption of reliance applies.

151. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

NO SAFE HARBOR; INAPPLICABILITY OF BESPEAKS CAUTION DOCTRINE

152. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

153. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

154. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the

"forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of BioVie who knew that the "forward-looking statement" was false. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions.

155. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this class action Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of BioVie who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

156. Plaintiff brings this action on behalf of all individuals and entities who purchased BioVie common stock during the Class Period, and were damaged thereby (the "Class"). Excluded from the Class are BioVie, its current and former directors and officers, and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the foregoing individuals and/or entities have or had a controlling interest (the "Class").

157. The Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, shares of BioVie common stock were actively traded on the Nasdaq. While the exact number of Class members is unknown at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members

in the proposed Class. Record owners and other Class members may be identified from records maintained by BioVie or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of November 8, 2023, BioVie had over 37 million shares of common stock outstanding. Upon information and belief, these shares are held by thousands of individuals located throughout the entire world. Joinder would be highly impracticable.

158. Plaintiffs' claims are typical of the claims of the Class members as all Class members are similarly affected by the Defendants' respective wrongful conduct in violation of the federal laws complained of herein.

159. Plaintiffs have and will continue to fairly and adequately protect the interests of the Class members and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

160. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by the Defendants' respective acts as alleged herein;

(b) whether the Defendants acted knowingly or with deliberate recklessness in issuing false and misleading statements concerning BioVie's NM101 Phase 3 clinical trial;

(c) whether the price of BioVie's securities during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and

(d) whether the Class members have sustained damages and, if so, what is the proper measure of damages.

161. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) and Rule 10b-5 Against All Defendants

162. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

163. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other Class members to purchase BioVie securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

164. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of BioVie securities in an effort to maintain artificially high market prices for BioVie securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

165. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about BioVie's NM101 Phase 3 clinical trial.

166. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of BioVie's value, performance, and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make

the statements made about BioVie's NM101 Phase 3 clinical trial under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of BioVie's common stock during the Class Period.

167. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents at BioVie during the Class Period and members of BioVie's management team or had control thereof; (2) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of BioVie, was privy to and participated in the creation, development and reporting of BioVie's SEC filings and public statements concerning BioVie's NM101 Phase 3 clinical trial; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendants and was advised of and had access to other members of BioVie's management team, internal reports, and other data and information about BioVie's NM101 Phase 3 clinical trial, at all relevant times; and (4) each Individual Defendant was aware of BioVie's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

168. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing risks associated with BioVie's NM101 Phase 3 clinical trial from the investing public and supporting the artificially inflated price of its common stock. As demonstrated by Defendants' misrepresentations concerning the fundamental problems and risks inherent in BioVie's NM101 Phase 3 clinical trial throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

169. As a result of the dissemination of materially false and misleading information and failure to disclose material facts, as set forth above, the market price of BioVie securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of BioVie securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other Class members acquired BioVie securities during the Class Period at artificially high prices and were or will be damaged thereby.

170. At the time of said misrepresentations and omissions, Plaintiffs and other Class members were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other Class members and the marketplace known the truth regarding the risks and flaws inherent in BioVie's NM101 Phase 3 clinical trial, which were not disclosed by Defendants, Plaintiffs and other Class members would not have purchased BioVie securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

171. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

172. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other Class members suffered damages in connection with their respective purchases and sales of BioVie securities during the Class Period.

173. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of common stock giving rise to the cause of action.

COUNT II

The Individual Defendants Violated Section 20(a) of the Exchange Act

174. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

175. The Individual Defendants acted as controlling persons of BioVie within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of BioVie's operations and/or intimate knowledge of the false information filed by BioVie with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of BioVie, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of BioVie's clinical test criteria, results, reports, press releases, public filings and other statements alleged by Plaintiffs to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

176. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of BioVie and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein and exercised the same.

177. As set forth above, BioVie and the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

178. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Class members suffered damages in connection with their purchases of BioVie's common stock during the Class Period.

179. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of common stock giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiffs as class representatives under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as class counsel;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

In accordance with Fed. R. Civ. P. 38(b), Plaintiffs demand a jury trial of all issues involved, now, or in the future, in this action.

Dated: June 21, 2024

Respectfully submitted,

ALDRICH LAW FIRM, LTD.

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and Lead Counsel for the Class

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of June, 2024, I electronically filed the foregoing document using the CM/ECF system which will send notification of such filing to the email addresses registered in the CM/ECF system, as denoted on the Electronic Mail Notice List.

/s/ John P. Aldrich
John P. Aldrich